PhRMA

August 26, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Draft Guidance on Placing the FDA Therapeutic Equivalence Code on Prescription Drug Labels and Labeling
Docket No. 98D-1266
64 Fed. Reg. 4434 (January 28, 1999);
64 Fed. Reg. 19792 (April 22, 1999)

The Pharmaceutical Research and Manufacturers of America (PhRMA) submit these additional comments on the draft guidance that the Food and Drug Administration made available on January 28, 1999, concerning the use in prescription drug labels and labeling of the therapeutic rating system established in the FDA Orange Book.[1] PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to research on medicines that allow patients to lead longer, healthier, and more productive lives.

FDA's premise in proposing this guidance was that "the use of therapeutic equivalence codes will contribute to the accurate and safe selection of generic products by pharmacists."[2] This also was the primary justification invoked by the generic industry in its support for the draft guidance. Pharmacists, however, do not agree that this guidance will help them select generic drugs safely.[3] That simple fact destroys the rationale on which the draft guidance (and the support of the generic industry) is based. FDA should heed this caution and abandon the draft guidance.

[1] PhRMA submitted comments on the draft guidance by the original deadline. When FDA reopened the comment period, PhRMA submitted brief additional comments. PhRMA stated that it would file additional comments to address new matters raised in comments filed by the generic drug industry after the close of the original comment period.

[2] 64 Fed. Reg. 4434, 4434 (January 21, 1999).
[3] Comments of the American Pharmaceutical Association, at 1 (June 21, 1999).

98D-1266 C25

The generic manufacturers argue that (a) the therapeutic ratings "will contribute to the accurate and safe selection of generic products *by pharmacists*"[4] and (b) the ratings will not mislead patients because they will be communicated only to sophisticated physicians and pharmacists.[5] The comments submitted both by pharmacists and by the generic industry itself completely undercut these two contentions.

First, as noted above, pharmacists oppose the draft guidance. They state that therapeutic ratings taken out of the Orange Book context are not comprehended by -- let alone useful to -- most health care practitioners. More importantly, they state that these cryptic, out-of-context therapeutic ratings will contribute to medication errors.[6] The National Coordinating Council for Medication Error Reporting and Prevention -- an organization in which PhRMA, the Generic Pharmaceutical Industry Association, and FDA participate -- concurred. For that reason, it recommended against including a second product name on the label.[7]

Second, the generic industry acknowledges that the "audience" for therapeutic rating statements includes patients as well as physicians and pharmacists. A trade association of generic manufacturers strongly advocates the prominent placement of the therapeutic rating in a manner calculated to reach the patient: "we would like to suggest that the therapeutic equivalence rating be allowed to be prominently displayed in the package insert *and in any patient information* provided with the dispensed product, as well as on the immediate container and carton labeling, if desired by the manufacturer."[8] If most health care practitioners cannot understand the therapeutic ratings without referring to the Orange Book, it goes without saying that those ratings -- AB, AT, BN, BX -- will mean nothing to the patient. The only thing about the therapeutic rating statement that will have any meaning to the patient is the brand name. That is what the generic industry wants the patient to see and the generic industry to benefit from (and, as discussed in previous PhRMA comments, that is also what can result in product confusion on the part of patients).

The generic manufacturers argue that the brand name manufacturers want to preserve the value of the trademarks on their pioneer drugs. That is true. The pioneer manufacturers have invested and continue to invest billions of dollars in new

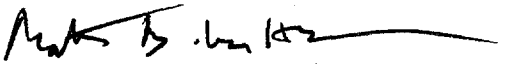
---

[4] Comments of Generic Pharmaceutical Industry Association, at 1 (April 1, 1999) (emphasis added).
[5] Comments of Barr Laboratories, Inc., at 2 (June 21, 1999).
[6] Comments of the American Pharmaceutical Association, at 1.
[7] Comments of the National Coordinating Council for Medication Error Reporting and Prevention, at 2 (June 21, 1999).
[8] Comments of Generic Pharmaceutical Industry Association, at 2 (emphasis added).

therapies with extremely valuable brand names. Congress sought to encourage such investment when it enacted the Drug Price Competition and Patent Term Restoration Act in 1984. Permitting therapeutic ratings on labeling would dilute the value of pioneer trademarks and could discourage the research and development that Congress has worked hard to promote.

The comments submitted on the proposed guidance demonstrate that there is extraordinary confusion about how the guidance would operate in practice. The comments also indicate that the proposed changes could increase the frequency of medication errors. In light of both factors, PhRMA urges FDA to abandon the draft guidance.

Sincerely yours,



Matthew B. Van Hook
Deputy General Counsel

cc: Jerry Phillips, CDER (HFD-730)